REMARKS

As a preliminary matter, attention is directed to the Request for Continued Examination (RCE) and to the Information Disclosure Statement that accompany this response.

The Invention

The invention relates to a method for the controlled release of an active substance into a use environment, for example the *in vivo* gastrointestinal tract or an *in vitro* test medium. The method requires preparing a controlled-release delivery composition comprising a core containing an active substance, and an asymmetric polymeric coating on the core. The polymeric coating (such as cellulose acetate in a preferred embodiment) is one that enables the dosage form to function in a high fat use environment, i.e., a use environment comprising at least about 0.5 wt% of dietary fat. The dosage form is, therefore, largely independent of whether the patient is in a fed or fasted state and of the nature of the food ingested by the patient. See Applicants' specification at page 10, lines 14-21 where these underpinnings are explained.

The operation and/or the therapeutic efficacy of dosage forms can be affected in an environment containing significant amounts of dietary fat. The invention thus represents (1) a selection of materials for use in (2) a method that employs a controlled release device having a core on which is coated an asymmetric membrane, such as the devices disclosed in US 5,612,059 to Cardinal et al. (hereinafter "Cardinal") (3) in a high fat environment, that is a use environment containing at least 0.5 wt% of dietary fat. Applicants respectfully submit that the invention is both novel and unobvious over the cited references inasmuch as none of the references (1) discloses Applicants' selection, i.e., that any of the asymmetric membrane materials disclosed therein would be preferable or better than any other asymmetric membrane materials also disclosed therein; (2) contains any suggestion or guidance that such would be the case; or (3) solves the problem of administering an active agent from an asymmetric membrane controlled release dosage form into a high fat use environment. Indeed, none of the references discloses anything relating to a method in which an asymmetric membrane controlled release device is required to function in a high fat use environment.

The Rejections and Applicants' Traversal

Claims 1-7, 9-13, 15-18, 21, and 22 were rejected under 35 USC 102(b) as anticipated by Cardinal. The examiner stated, in pertinent part:

Cardinal discloses a controlled release device comprising an active core and one or more asymmetric membranes (abstract; column 10, lines 26-63; and claims). Asymmetric coating comprises cellulosic material including cellulose acetate (column 7, lines 45-67; and claims 19-28). Active comprises drugs (column 10, lines 18-25). Cardinal further discloses controlled release of active substance is by diffusion and/or osmotic pumping (abstract; column 9, lines 20-65; and column 10, lines 52-57).

The claimed properties, such as dietary fat in the use environment, and time to release 50% of the active agent into the use environment is at least 0.5 fold, but less than 2.0 fold the time required for the composition to release 50% of said active agent into a control use environment comprising less than about 0.1% dietary fat, are silent. However, Cardinal teaches the use of the claimed polymeric coating, e.g., cellulose acetate as an asymmetric membrane for a controlled release of active agent to the same use environment, oral administration. Accordingly, the use identical structures being administering to the same environment of use necessitates similar properties desired by the applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Applicants respectfully traverse the rejection on the basis that Cardinal does not disclose Applicants' method. In particular, Cardinal cannot anticipate because Cardinal does not disclose a method involving administration into a use environment comprising at least 0.5 wt% of dietary fat. The fact that Cardinal discloses asymmetric controlled release dosage forms that could be used in a high fat use environment is not novelty-destroying if Cardinal does not disclose using them in a high fat use environment. Indeed, Cardinal contains no disclosure at all relating to the problems generated in a high fat environment and/or how to avoid, circumvent or otherwise solve the problem of operating therein.

Clearly, Cardinal does not disclose Applicants' method, it being additionally noted that the Examiner did not cite to any textual portion of Cardinal that would support a different conclusion. Cardinal contains no disclosure one way or the other that any dosage form therein might be affected by fat in the use environment, or that any particular asymmetric membrane material is preferred or better than any other for operating in a high fat environment. Operating in a high fat environment is thus an element present in Applicants' claims that is not disclosed in Cardinal. It is well accepted that t to anticipate,

every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001). Thus, because the element of administering into a use environment comprising at least about 0.5 wt% of dietary fat is missing from Cardinal, Applicants' method cannot be anticipated.

Citing to In re Spada, the Examiner appeared to take the position that the capability for operating in a high fat environment is simply a property that is necessarily present in identical chemical structures. Applicants respectfully disagree. Rather than being simply a property, the capability for operating in a high-fat environment is an element that is affirmatively required by the instant claims. Further, Applicants' examples demonstrate that not all materials that can be used to make an asymmetric membrane are suitable for use in a high fat use environment. There is no guidance provided in Cardinal (or any of the references) that would lead one of ordinary skill in the art to choose any asymmetric membrane material over any other for use in a high fat environment.

In different words, it is not possible for a Applicants' method claims to be anticipated by a reference that does not disclose the method. Cardinal is utterly devoid of any teachings or disclosure relating to administering an active agent in an asymmetric membrane controlled release dosage form into a high fat use environment. The Examiner's comment that

> [w]hen the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established..."

is noted. Applicants respectfully disagree, however, because Applicants are not claiming a structure or composition, nor do Applicants claim a process for producing the structure or composition. Applicants claims are directed to a method, in an asymmetric membrane controlled release device, for the controlled release of an active substance into a use environment containing at least a minimum level of dietary fat. None of the disclosures in any of the references relates to such a method.

The Best case cited by the Examiner is inapposite. In re Best relates to claims that were directed to a zeolitic molecular sieve catalyst *per se* and to a process for producing the catalyst, in which the decision stated that the claimed product was the unique result of the claimed process. In re Best, at 432. In contrast to the facts in Best, none of the instant claims is directed to a dosage form *per se* or to a method for producing it.

Rather, the instant claims are directed to a method for the controlled release of an active substance into a use environment that contains at least about 0.5 wt% of dietary fat. No analogous claim was at issue in Best.

The claims stand variously rejected under 35 USC 103(a) over Cardinal in view of Faour (US 6,004,582), and in view of Faour taken with FDA press release or Camden (US 6.136,835), each of the secondary references having been cited to fill in one or more elements missing from Cardinal. Faour appears to have been cited for its disclosure of certain active agents and a taste masked finish coating. FDA press release appears to have been cited for its disclosure of improved package inserts that include boxed warnings, indications, and dosage and administration (Office action, page 4, last paragraph). Camden appears to have been cited for similar reasons (Office action, page 5, first full paragraph).

Applicants respectfully traverse each of the obviousness rejections on the basis that, regardless of what each of the secondary references purports to teach individually, none of the secondary references teaches anything relating to administering an active ingredient into a high fat environment with any controlled release device, much less an asymmetric membrane controlled release device. Accordingly, none of the secondary references can fill in the gaps left by the primary reference, Cardinal, and it is requested that all of the obviousness rejections be withdrawn.

It is accordingly respectfully submitted that there are no issues outstanding and that, in view of the foregoing comments, Applicants' claims are patentable. A Notice of Allowance is respectfully submitted.

Respectfully submitted,

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